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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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April 20, 2015

Dr. Debra A. Draper
Director
Health Care Team
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Dr. Draper:

Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, May 4, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green Ranking Member, Subcommittee on Health

Attachment

Attachment—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. HRSA had been preparing a regulation to address the definition of a patient and hospital eligibility, but withdrew its proposal last year following a May 2014 federal district court ruling which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA has explained that the agency will be proposing *guidelines* later this year to address those issues. Are you aware of any other health care agency in recent history whose hands have been tied in this manner, by not being able to write rules governing the program they administer? In the interest of government accountability and program integrity, is this concerning to you?

2. GAO cites the increase in hospital participation and the lack of clear guidance in a *patient definition* as the key reason for risks associated with drug diversion under the program. Did GAO track the scope or end of drug diversion occurring in the projects it examined—in other words, do we know if prescription drugs were improperly distributed for illicit purposes?

3. Around 20% of covered entities are private, non-profit hospitals that become eligible, in part, through their DSH percentage. However, these "DSH hospitals" account for over 80% of the discounts under the program. At the same time, recent reports question whether the use of the DSH percentage as eligibility criteria for these private, non-profit hospitals is appropriate in the first place. For example, MedPAC has noted "little evidence of a relationship between the DSH payments hospitals receive and the amount of uncompensated care they provide[,]" which raises doubts about 340B program's reliance on DSH for eligibility purposes. Are there are options that would establish a better charity care proxy for hospital entry into the program? What criteria that might better reflect a hospital's uncompensated care that would justify entry into the program?

4. MedPAC's recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that the Medicare's drug reimbursement is ASP+6, while the 340B program yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations—cautions or encouragements—would you offer Congress on this policy proposal?

The Honorable Tim Murphy

1. The September 2011 GAO report (*Drug Pricing: Manufacturer Discount in the 340B Program Offers Benefits, But Federal Oversight Needs Improvement*) states, "Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report." (Page 10) Does this mean that a hospital or hospital system could acquire a 340B eligible clinic and purchase their outpatient drugs at the 340B discounted price through these clinics?

    a. In the GAO's review of the 340B program, did you identify any examples of hospitals or hospital systems using the program in this manner?

    b. Would you consider the use of the program in this manner to be consistent with the original intent of the program?